HF1-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

M879N

Refer to: CFN 1119189

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

May 2, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Jerome Leight, President
LKC Technologies, Inc.
2 Professional Drive, Suite 222
Gaithersburg, Maryland 20879

Dear Mr. Leight:

During a Food and Drug Administration (FDA) inspection of your facility on April 15, 1997, our investigator determined that your firm manufactures ophthalmic diagnostic units. The units are medical devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for, manufacturing, packing, storage, or installation, do not conform to the Good Manufacturing Practice (GMP) for Medical Devices Regulations, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish an adequate quality assurance program. For example, the quality assurance program fails to provide for a documented review of production records, in that device history records lacked the approval signature and date of the final review.

2. Failure to maintain device history records to demonstrate that the device is manufactured in accordance with the device specifications. For example, the following device history records were noted to be incomplete and/or lacked the operator/assembler's initials and dates:

a. The data cross-outs on pages 4, 6, 10, etc., of the device history record for a UTAS E-2000 Electrodiagnostic System, serial number "0320," were not dated and initialed by the correcting individual.

b. The device history record for a UTAS E-2000 Electrodiagnostic System, serial number "0322," failed to indicate that the "Final Test" (software virus scan) was performed.

c. The device history record for a UTAS E-3000 Electrodiagnostic System, serial number "U3KI112/U3KG112," failed to document the Impedance Oscillator Test and Notch Filter data on page 6 of the record.

3. Failure to thoroughly review, evaluate, and maintain written and oral complaints pertaining to the identity, quality, durability, reliability, safety, effectiveness, or performance of your devices. Your firm is required to maintain a written record when an investigation is made. When a decision not to conduct an investigation is made, a formally designated unit shall maintain a record that includes the reason and the name of the individual(s) responsible for such a decision.

4. The device master records were not available for FDA review at the time of the inspection.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA-483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective action.

We acknowledge that you have submitted to this office a response concerning our investigator's observations noted on the form FDA-483. We have reviewed your response and conclude that the majority of it is adequate. However, we do not agree with your response to FDA-483, item 4. While it is important to maintain the device records in a safe place, all required records shall be maintained at the manufacturing establishment or other location that is reasonably accessible to responsible officials of the manufacturer and to employees of the FDA [21 CFR 820.180]. Your policy to maintain the device master records in locked storage, in your absence, prevents the potential need for review by production employees, the quality assurance unit, and our investigator.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

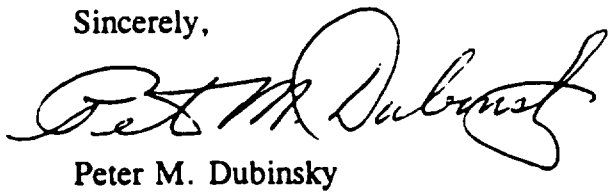
Additionally, no pre-market submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to the Food and Drug Administration, Richmond Resident Post, 10710 Midlothian Turnpike, Suite 424, Richmond, Virginia 23235, to the attention of Scott J. MacIntire, Compliance Officer. Mr. MacIntire may be reached at 804-379-1627; Extension 14.

Sincerely,



Peter M. Dubinsky
Acting Director, Baltimore District

bcc: [redacted]; HFI-35 (purged), [redacted]

TRACKING #: 97-BLT-30